

§ 184.1610

Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.23.1).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1610 Potassium alginate.

(a) Potassium alginate (CAS Reg. No. 9005-36-1) is the potassium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Potassium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

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Category of food	Maximum level of use in food (as served) (percent)	Functional use
Confections and frostings, § 170.3(n)(9) of this chapter.	0.1	Stabilizer, thickener, § 170.3(o)(28) of this chapter
Gelatins and puddings, § 170.3(n)(22) of this chapter.	0.7	Do.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	0.25	Do.
All other food categories.	0.01	Do.

(d) Prior sanctions for potassium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982]

§ 184.1613 Potassium bicarbonate.

(a) Potassium bicarbonate (KHCO₃, CAS Reg. No. 298-14-6) is made by the following processes:

(1) By treating a solution of potassium hydroxide with carbon dioxide;

(2) By treating a solution of potassium carbonate with carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter; nutrient supplement as defined in §170.3(o)(20) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1619 Potassium carbonate.

(a) Potassium carbonate (K_2CO_3 , CAS Reg. No. 584-08-7) is produced by the following methods of manufacture:

(1) By electrolysis of potassium chloride followed by exposing the resultant potassium to carbon dioxide;

(2) By treating a solution of potassium hydroxide with excess carbon dioxide to produce potassium carbonate;

(3) By treating a solution of potassium hydroxide with carbon dioxide to produce potassium bicarbonate, which is then heated to yield potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 240, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; nutrient supplement as defined in §170.3(o)(20) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1622 Potassium chloride.

(a) Potassium chloride (KCl, CAS Reg. No. 7447-40-7) is a white, odorless solid prepared from source minerals by fractional crystallization or flotation. It is soluble in water and glycerol and has a saline taste at low concentration levels.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 241, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter; as a flavoring agent as defined in §170.3(o)(12) of this chapter; as a nutrient supplement as defined in §170.3(o)(20) of this chapter; as a pH control agent as defined in §170.3(o)(23) of this chapter; and as a stabilizer or thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Potassium chloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51614, Nov. 10, 1983]